Registration Decision RD2015-11

# Spinosad

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## Registration Decision for Spinosad

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of Spinosad Technical Insecticide and Ortho Home Defense Max Ant Bait Stations, containing the technical grade active ingredient spinosad, to be used in a bait station to control ants and ant colonies.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

These products were first proposed for registration in the consultation document[1] Proposed Registration Decision PRD2015-05, *Spinosad*. This Registration Decision[2] describes this stage of the PMRA's regulatory process for spinosad and summarizes the Agency's decision and the reasons for it. The PMRA received no comments on PRD2015-05. This decision is consistent with the proposed registration decision stated in PRD2015-05.

For more details on the information presented in this Registration Decision, please refer to the Proposed Registration Decision PRD2015-05, *Spinosad* that contains a detailed evaluation of the information submitted in support of this registration.

## What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act* "...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment. These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

## What Is Spinosad?

Spinosad is a fermentation product of the bacterium *Saccharopolyspora spinosa* that must be eaten by the pest to be effective. It acts on insect nerves, causing paralysis and death. Products containing spinosad are also registered for use on greenhouse food and ornamental crops, outdoor food and ornamental crops and turf against a wide variety of insect pests.

## Health Considerations

### Can Approved Uses of Spinosad Affect Human Health?

**Ortho Home Defense Max Ant Bait Stations, containing spinosad, is unlikely to affect your health when used according to label directions.**

Potential exposure to spinosad may occur when handling and applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses more than 100-times higher (and often much higher) than levels to which humans are normally exposed when pesticide-containing products are used according to label directions.

In laboratory animals, technical spinosad was of low acute toxicity via the oral, dermal and inhalation routes of exposure. It was minimally irritating to the eye and non-irritating to the skin, and did not cause an allergic skin reaction.

The end-use product, Ortho Home Defense Max Ant Bait Stations, was of low acute toxicity via the oral, dermal and inhalation routes of exposure. It was minimally irritating to the eye and non-irritating to the skin, but did cause an allergic skin reaction. Consequently, the statement, "Potential Dermal Sensitizer" is required on the label.

Spinosad did not cause cancer in laboratory animals and was non-genotoxic. There was no indication that spinosad caused damage to the nervous system. Health effects in animals given repeated doses of spinosad included effects on the thyroid gland, lymphoid tissues, kidneys, spleen and blood system. Spinosad did not cause birth defects in laboratory animals. When spinosad was given to pregnant animals, fetal death was observed at doses which produced significant toxicity in the mothers. There is uncertainty regarding the susceptibility of lungs following repeated inhalation exposure, necessitating the application of extra protective factors for inhalation risk assessment to further reduce the allowable level of human exposure to spinosad.

The risk assessment protects against the effects of spinosad by ensuring that the level of human exposure is well below the lowest dose at which these effects occurred in animal tests. In the case of Ortho Home Defense Max Ant Bait Stations, potential exposure is considered to be negligible as the product is an impregnated material bait that is enclosed in a ready-to-use bait station.

**Risks in Residential and Other Non-Occupational Environments**

**Residential risks are not of concern when Ortho Home Defense Max Ant Bait Stations is used according to label directions and instructions.**

Residential exposures to spinosad are considered negligible when adults place, replace, and dispose of Ortho Home Defense Max Ant Bait Stations ready-to-use ant bait stations. Adults, youth, and children are not expected to be exposed by direct skin contact with spinosad residues since the bait is contained inside a sealed bait station. In addition, the label states to keep bait stations out of reach of children.

Residential exposures (application and post-application) to the end-use product are not expected to result in unacceptable risk when this product is used according to label directions. Precautionary and hygiene statements on the label are considered adequate to protect individuals from unnecessary risks due to placement or post-placement exposures.

Therefore, health risks to residents and bystanders are not of concern.

**Occupational Risks From Handling Ortho Home Defense Max Ant Bait Stations**

No occupational scenarios were included for this domestic product.

## Environmental Considerations

### What Happens When Spinosad Is Introduced Into the Environment?

**When spinosad is used as ant bait in enclosed bait stations, for use indoors or outdoors around the perimeter of homes, there is very limited potential for release of spinosad to terrestrial or aquatic environments.**

Wild birds and mammals, honeybees, earthworms and beneficial insects will not be exposed to spinosad in the bait stations and, therefore, the risk is expected to be negligible. Similarly, spinosad is not likely to enter surface waters from this use and, as such, risks to fish and other aquatic life are also negligible.

## Value Considerations

### What Is the Value of Ortho Home Defense Max Ant Bait Stations?

**Ortho Home Defense Max Ant Bait Stations contains ant bait that kills ants and ant colonies. It is a domestic class product for use indoors and outdoors around the perimeter of homes.**

Spinosad, formulated as bait in Ortho Home Defense Max Ant Bait Stations, kills ants and ant colonies. This product is not intended for use against carpenter ants. Spinosad is a new mode of action for use against ants in Canada.

## Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label of Ortho Home Defense Max Ant Bait Stations to address the potential risks identified in this assessment are as follows.

### Key Risk-Reduction Measures

#### Human Health

The primary label includes the phrase "KEEP OUT OF REACH OF CHILDREN", and in the Precautions section, statements include, "Keep away from food and drinks…" and "Do not eat, drink and smoke during use".

**Environment**

The presence of petroleum distillate in the product warrants environmental hazard statements on the Ortho Home Defense Max Ant Bait Stations label. A label statement regarding the disposal of used product is also required to prevent contamination of ponds, waterways and ditches.

## Other Information

The relevant test data on which the decision is based (as referenced in PRD2015-05, *Spinosad*) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act*.